

REMARKS

Applicants wish to thank the Examiner for the courteous and helpful interview conducted on March 22, 2005 with Mr. Spear. Claims 1-34 are currently pending for the Examiner's consideration, with claims 1, 11, 13, 18, 29, and 30 being the independent claims. As noted during the interview, claims 29 and 30 are not included in any of the rejections in the Office Action.

Double-Patenting

As noted on the Interview Summary dated March 22, 2005, the obviousness-type double patenting rejection was to have been based upon prior U.S. Patent No. 6,495,164 ("the '164 patent") alone. Filed herewith is a Terminal Disclaimer to Obviate a Double Patenting Rejection Over a "Prior" Patent executed by the assignee of the above-captioned application for the '164 patent. A Statement Under 37 C.F.R. § 3.73(b) establishing the right to act on behalf of the assignee with regard to the above-captioned application is also filed herewith. The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991). The filing of a terminal disclaimer serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection. *Id.*; M.P.E.P. § 804.02. Based upon filing of the Terminal Disclaimer and accompanying fee, Applicants respectfully submit that the obviousness-type double patenting rejection should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected independent claims 1 and 33, and dependent claims 2-10, 20, 22-28, 31, and 34, under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,306,425 ("the '425 patent"). The Examiner has rejected independent claims 1, 11, 13, 18, and 33 and dependent claims 2-28 and 31-34 under 35 U.S.C. § 103(a) as being unpatentable over the '425 patent in view of U.S. Patent No. 6,034,175 ("the '175 patent"). As recognized by the Examiner and noted on the Interview Summary, neither the '425 patent nor the '175 patent discloses or suggests a viscosity for the fluid phase of the suspension of microparticles in the

range of 20 cp to 600 cp at 20 °C to provide injectability through a needle of 18-22 gauge or medically acceptable size, as required by all of the claims.

In the Office action, the Examiner incorrectly relied on the teachings in the '425 patent regarding the viscosity of the polymer that is used to make the microparticles themselves, which is totally inapposite to the claimed invention. In addition, the Examiner incorrectly asserted that an increase in viscosity would "retain an advantage of diminishing the discomfort from injection." Such an assertion is contrary to the conventional teachings cited in the background of the application (*see* pages 2 and 3 of the application as originally filed). The inventors have unexpectedly discovered that injectability is improved, and *in vivo* injectability failures significantly and unexpectedly reduced, by increasing the viscosity of the fluid phase of an injectable suspension. This is in contrast to conventional teachings that an increase in the viscosity hinders injectability and syringeability. Viscosity is typically kept low to make the suspension easier to inject (*i.e.*, low force on the syringe plunger).

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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